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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/072,320	02/07/2002	Russell Mumper	NANO:002USD1	5127

7590 10/09/2009
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EXAMINER

ROGERS, JAMES WILLIAM

ART UNIT	PAPER NUMBER
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1618

MAIL DATE	DELIVERY MODE
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10/09/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/072,320	Applicant(s) MUMPER ET AL.	
	Examiner JAMES W. ROGERS	Art Unit 1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 August 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 33,34,36-57,63 and 64 is/are pending in the application.
- 4a) Of the above claim(s) 47-50 and 52-55 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 33,34,36-46,51,56,57,63 and 64 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicants amendments to the claims and specification filed 08/03/2009 have been entered.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 08/03/2009 has been entered.

Election by Original Presentation

Newly resubmitted claim 47 is directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: in the office action filed 02/02/2004 applicants elected to prosecute proteins or peptides as the molecule of interest. Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claim 47 is withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

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The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 33-34,36-46,51,57-57 and 62-64 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The first instance of new matter is the exclusion of natural polymers, for support applicants contend that natural polymers is a title of a reference found in the specification and this positive recitation provides the basis for exclusion. The examiner disagrees, in order for an ingredient of a composition to be excluded from that composition it must either be positively recited within the specification as an ingredient of that composition or the specification must teach the exclusion of such an ingredient from the composition. In this case the recitation of natural polymer is a title of a reference and applicants never recited the term natural polymers within their own composition or a description to exclude natural polymers. Applicant's second assertion that they use the term "natural" in the specification at page 12 and can therefore exclude natural polymers is also not seen as persuasive by the examiner, the recitation of natural is referring to the molecule of interest not natural polymers. Applicants also seem to suggest that since they teach synthetic polymers they should be able to exclude the opposite of synthetic which is natural, the examiner disagrees with this argument since natural polymers are never recited positively or negatively for use in the composition. Furthermore while there is

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support within the specification for anionic mucoadhesive polymers the examiner could not find support for anionic pH-sensitive film forming polymers. The examiner also could not find a positive or negative recitation that stated the composition was free of any neutral polymers. Any negative limitation or exclusionary proviso must have basis in the original disclosure if alternative elements are positively recited in the specification, they may be explicitly excluded in the claims. See *In re Johnson*, 558 F.2d 1008, 1019, 194 USPQ 187, 196 (CCPA 1977) (“[the] specification, having described the whole, necessarily described the part remaining.”). See also *Ex parte Grasselli*, 231 USPQ 393 (Bd. App. 1983), *aff’d mem.*, 738 F.2d 453 (Fed. Cir. 1984). The mere absence of a positive recitation is not basis for exclusion. Regarding claim 63, while applicants do have support for the data points of 2:1, 3:1 and 4:1 for the ratio of Noveon/Eudragit in the examples and figure 3, these three data points do not give support to claim the broader range of any ratio between about 2:1 to about 4:1.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 33-34,36-37,42-46,56-57 and 64 are rejected under 35 U.S.C. 103(a) as being unpatentable over Slavtcheff et al (US 6,270,783 B1) in view of Suzuki et al. (US 4,715,369, cited previously).

Slavtcheff discloses adhesive cosmetic strips which includes a backing layer and an adhesive composition, the adhesive composition included dry to touch adhesives that normally contained a fluid and a structuring agent such as Carbomer in addition to

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a polymer, the polymer could be selected from anionic film forming polymers. See abstract, claims, col 4 lin 61-col 5 lin 29 and col 6 lin 4-15. While Slavtcheff is silent on the ratio of the structuring polymer carbomer to film former, however such adjustments to the concentration of ingredients within an adhesive is no more than ordinary and routine optimizations. One of ordinary skill in the art has good reason to optimize the concentrations of ingredients within an adhesive composition for cosmetic use in order to optimize the stickiness of the adhesive. For instance one would optimize the stickiness so that the patch, bandage etc. provided the desired adhesion to skin without being so sticky as to cause skin irritation or injury from pulled hair for example.

Slavtcheff does not disclose the thickness of the cosmetic strip or the use of a wax backing layer. These deficiencies however are taught by Suzuki as described in the previous office action filed 01/02/2009 Suzuki discloses the advantages of using a thin layer for adhesive patches and the use of a wax backing layer. Suzuki disclosed that thin films advantageously alleviates the feeling of touchy discomfort and makes itself applicable to flexure. Thus from the disclosure of Slavtcheff and Suzuki applicants claimed thin bi-layer wax film containing an adhesive containing only anionic polymers and a wax backing layer would have been obvious since the two references are related to the same general field of adhesives for personal use. Thus one of ordinary skill in the art would have a high expectation of success in using the backing layer of Suzuki and substituting it for the backing layer of Slavtcheff. The reason to make such a modification to Slavtcheff would be that the thin backing layer of Suzuki in combination with the adhesive of Slavtcheff would provide a thin adhesive strip which would

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advantageously alleviate the feeling of touchy discomfort and make itself applicable to flexure.

Claims 33,34,36-46,51,56,57,63 and 64 are rejected under 35 U.S.C. 103(a) as being unpatentable over Slatcheff et al (US 6,270,783 B1) in view of Suzuki et al. (US 4,715,369) in view of Mantelle et al. (US 6,562,363 B1, cited previously).

Slatcheff and Suzuki are disclosed above as well as the reasoning for why their combination is obvious. Neither Slatcheff or Suzuki describe the use of the specific mucoadhesive polymer Noveon or the specific film forming polymers such as Eudragit claimed in dependent claims 38-41. However Mantelle as disclosed in the previous office action filed 05/01/2009 discloses the use of Noveon and Eudragit polymers in adhesive compositions for personal use. Since all of the references above are related to the same general field of endeavor it would have been prime facie obvious at the time of the invention to a person of ordinary skill in the art to modify the polymers disclosed in Slatcheff and add the polymers disclosed within Mantelle. It is generally considered to be prime facie obvious to combine compounds each of which is taught by the prior art to be useful for the same purpose in order to form a composition that is to be used for an identical purpose. The motivation for combining them flows from their having been used individually in the prior art, and from them being recognized in the prior art as useful for the same purpose. As shown by the recited teachings, instant claims are no more than the combination of conventional components of adhesives for personal use. It therefore follows that the instant claims define prime facie obvious subject matter.

Conclusion

No claims are allowed at this time.

Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James W. Rogers, Ph.D. whose telephone number is (571) 272-7838. The examiner can normally be reached on 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Hartley can be reached on (571) 271-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you

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have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Michael G. Hartley/

Supervisory Patent Examiner, Art Unit 1618